Processa Pharmaceuticals

Corporate Presentation
January 2020

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Processa Pharmaceuticals

Processa Pharmaceuticals Overview

Corporate Facts (OTCQB: PCSAD)

- Formed as private company in 2016 and became public as Processa in 2017
- Raised total cash of $11.8 M since 2016
- Over $40M invested in drugs prior to Processa in-licensing them
- 2019 overhead and internal R&D costs, including salaries was less than $2.5 M
- 5.5 million shares outstanding
- Working toward Nasdaq up-list in Q1 - 2020

Pipeline Focus

- Acquiring & developing drugs for patients needing treatments to extend survival or improve quality of life
- Each drug in our portfolio must have the potential for a high ROI
- Each drug in our portfolio must already have some clinical evidence of efficacy

Competitive Advantage

- Processa staff has previously trained FDA reviewers and conducted FDA funded research
- Our development team has a track record of more than 30 FDA approvals and more than 100 FDA meetings & value creation
- Our existing portfolio of drugs have the potential for a high ROI and existing clinical evidence

12-18 Month Upcoming Milestones

- PCS-499: Phase 2 positive trial completed; meet with FDA regarding remaining development, SPA, pivotal trial; and initiate a Phase 2b/3 trial
- PCS-100: Conduct toxicology studies to better define therapeutic window and initiate Phase 1 adult MTD study
- 3rd drug: Negotiating the in-licensing of 3rd drug with evidence of clinical efficacy

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Our People Are a Competitive Advantage

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Our People Lead to Success

- Established and proven Executive Team with 20+ years of biotech management experience
  - Most recently helped transform Questcor Pharmaceuticals from $15M market cap in 2007 to $5.6B in 2014 when acquired by Mallinckrodt
- Development Team has a proven record of success and has worked together in other companies
  - More than 30 years of experience developing drugs
  - Trained FDA reviewers, conducted FDA sponsored research to support 4 FDA Guidances, helped in the writing of 3 FDA Guidances
  - FDA Advisory Committee involvement as Committee Member & Sponsor
  - Involved with more than 30 FDA approvals and more than 100 FDA meetings, the most recent approval was for Acthar which was a key value creation event for Questcor Pharmaceuticals
  - Agnostic to therapeutic area having worked with every FDA Drug Review Division

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Our Leadership

David Young, Pharm.D., Ph.D., CEO, Chairman of the Board

- Former Board Member, CSO of Questcor Pharmaceuticals, $15M Market Cap to $5.6B in 7 years
- Former President, AGI Therapeutics; Founder & CEO, GloboMax
- Former Instructor of FDA Reviewers; Former FDA Advisory Committee Member

Patrick Lin, Chief Business and Strategy Officer and Director, Board of Directors

- 20 Years Financing and Investing Experience in Biopharma Sector;
- 25 years on Wall Street involved with over 500 IPOs and follow on offerings
- Principal/Founder Primarius Capital, Focused on Small Cap with Numerous $3B+ Mkt Cap Winners
- Former E*Offering Co-Founding Partner Growing Company to 200 Employees and $80M Rev. During 1st Year; Former Principal at Robertson Stephens & Co.

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Our Leadership

Sian Bigora, Pharm.D., Chief Development Officer

- Former VP, Regulatory Affairs at Mallinckrodt, Questcor Pharmaceuticals, AGI Therapeutics, GloboMax
- Former Instructor of FDA Reviewers

James Stanker, CPA, Chief Financial Officer

- 30 years of Financial and Executive Leadership Experience
- Former Audit Partner at Grant Thornton and Global Head of Audit Quality for Grant Thornton International; Former CFO at NASDAQ Listed Company and a Privately Held Company
- Currently on the Board of Directors and Chairman of the Audit Committee of GSE Systems, Inc. (NYSE MKT: GVP)

Wendy Guy, Chief Administrative Officer

- Former Senior Manager in Business Operations at Questcor, AGI Therapeutics, GloboMax with 20 Years Experience in Corporate Management, HR and Finance

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Our Strategy and Competitive Advantage

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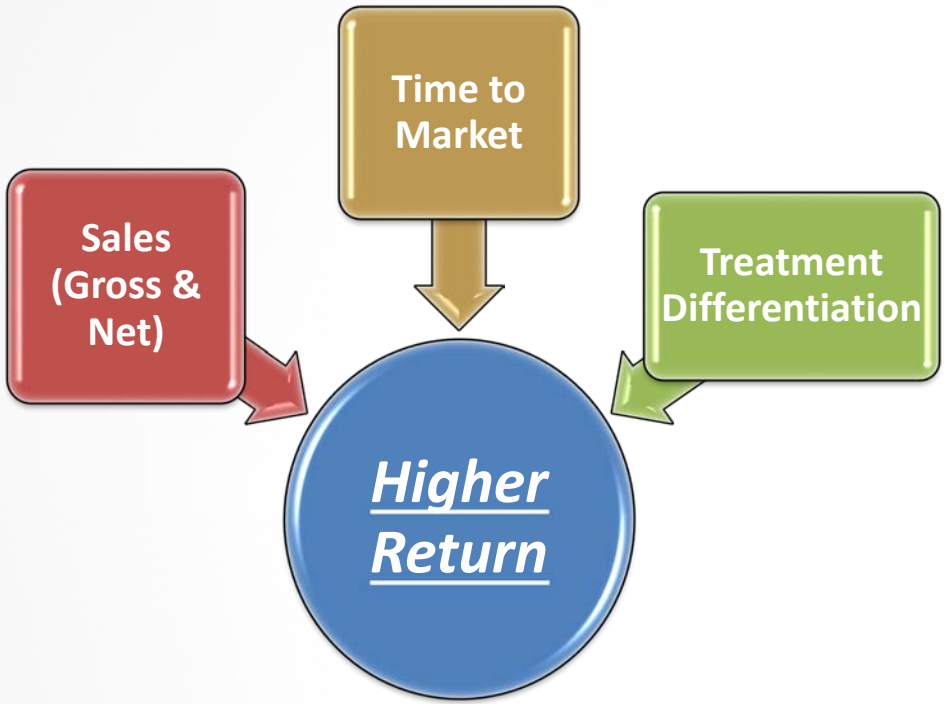
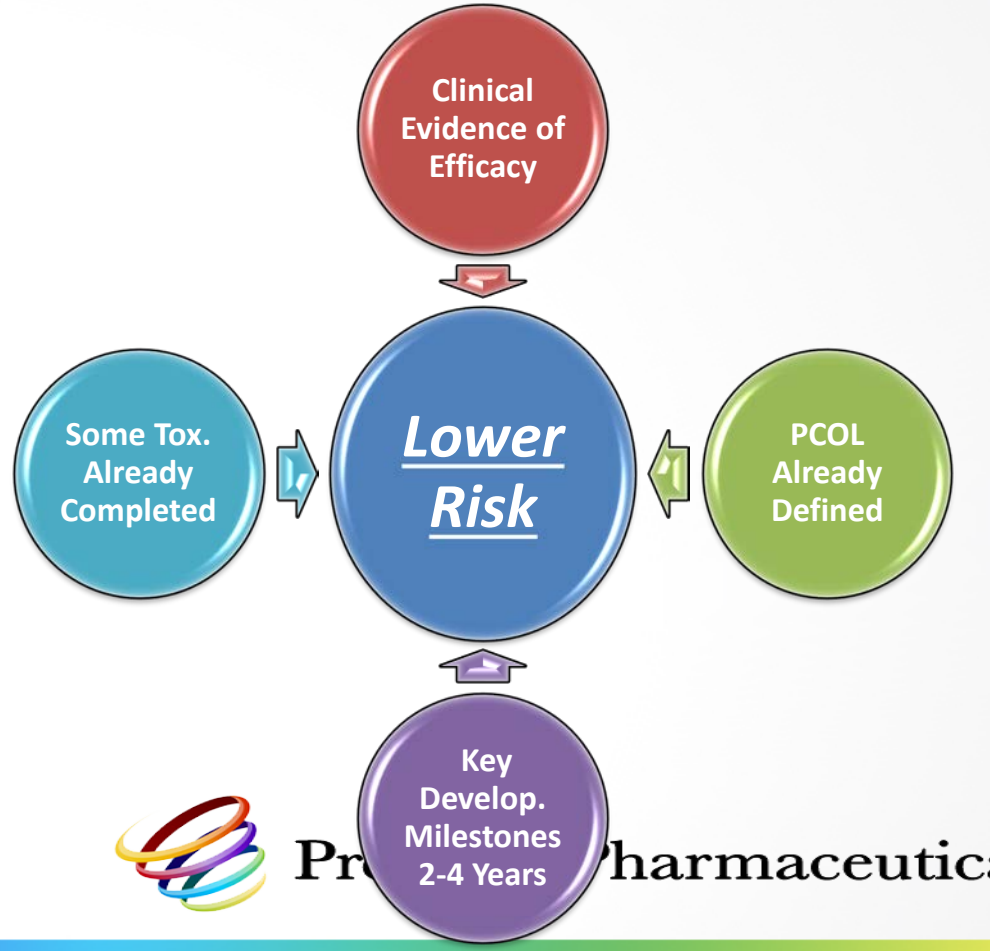
Our Strategy: Obtain Drugs with High Potential Value, Lower Risk of Failure during Development

Increase return on investment (ROI) by selecting drugs and indications with higher potential gross sales, faster time to market, & differentiation from existing treatments

Decrease risk of failure by selecting drugs with some clinical evidence of efficacy/safety, pharmacology-tox understood, & value added milestones in 2-4 years





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Competitive Advantage: Processa Approach to Obtaining Drug Approval

We Know The Way To The FDA

Over the Last 25+ Years, Our Team Has Refined a Regulatory Science Platform or Approach for the Development of Drugs for FDA Approval

- The Regulatory Science Platform is based on our experience teaching FDA reviewers, conducting research funded by FDA for FDA Guidances, writing FDA Guidances, developing drugs for FDA approval, and meeting with FDA as a colleague and as a sponsor
- R&D studies are conducted to provide the scientific foundation upon which FDA will make regulatory decisions, not for scientific knowledge
- Processa does not focus on one therapeutic area but has the knowledge and expertise to obtain drug approvals across therapeutic areas having successfully interacted with almost every FDA division

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Processa Present Portfolio:
PCS-499 & PCS-100

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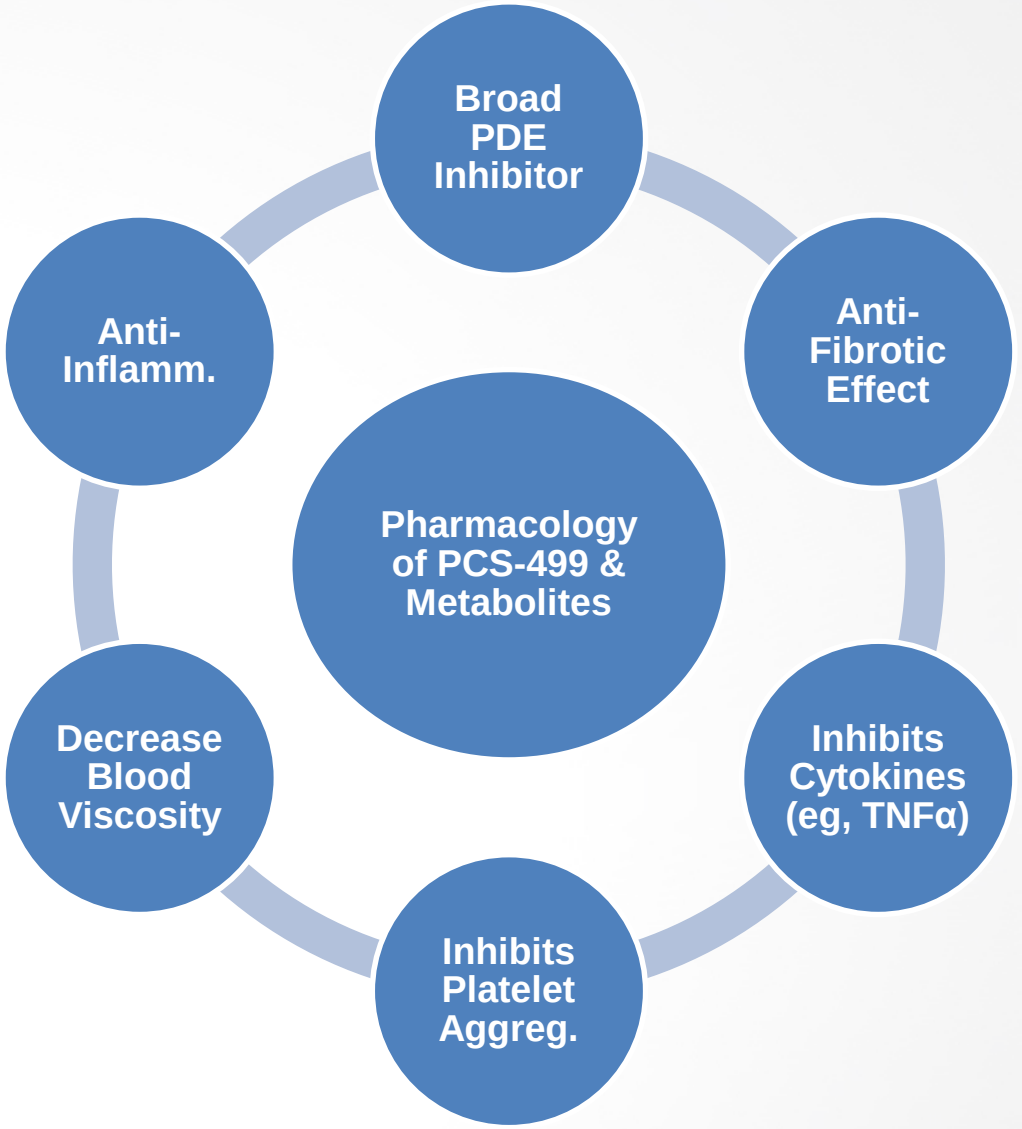
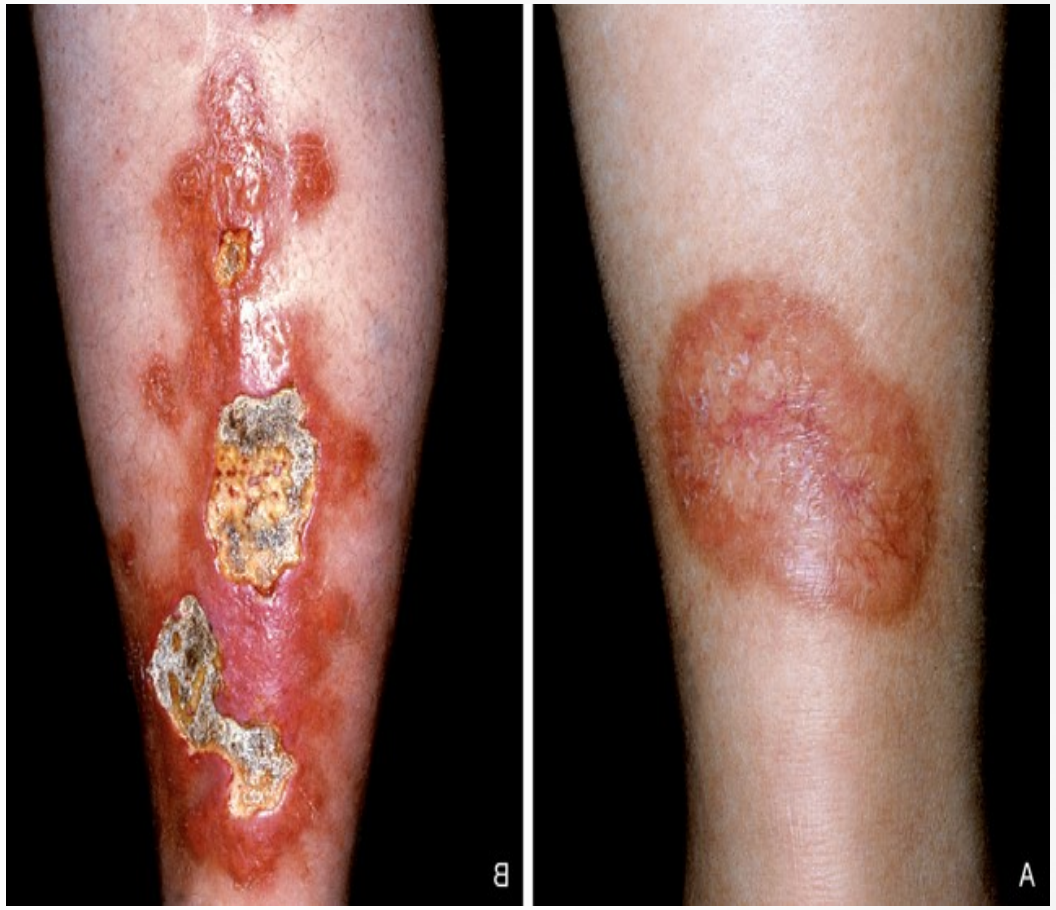
PCS-499: Deuterated Analog of a Major Active Metabolite of FDA Approved Pentoxifylline (PTX)

- PCS-499 metabolizes to same active moieties as PTX (including reversibly metabolized to PTX itself) but the metabolite profile is different after PCS-499 administration than PTX (i.e., the % exposure to various active metabolites and administered drug is different)
- PCS-499 and active metabolites have a diverse pharmacology profile
- Originally developed by Concert Pharmaceuticals in Diabetic Nephropathy, taken to an end of Phase 2 meeting



Patient Need: No Approved Treatment for Necrobiosis Lipoidica (NL)

- Occurs in women/men 20 – 60 y/o
- Potential to last for months or years
- Skin becomes necrotic; 30% of patients have painful ulcerations; complications - infections, amputation, squamous cell cancer
- No standard of care or FDA approved treatment; no known biotech or pharma company developing a drug for NL; Dermatologists mainly use topical steroids and other drugs with poor response; Pentoxifylline (PTX) is not approved for NL but has been used off-label successfully in a small percentage of NL patients



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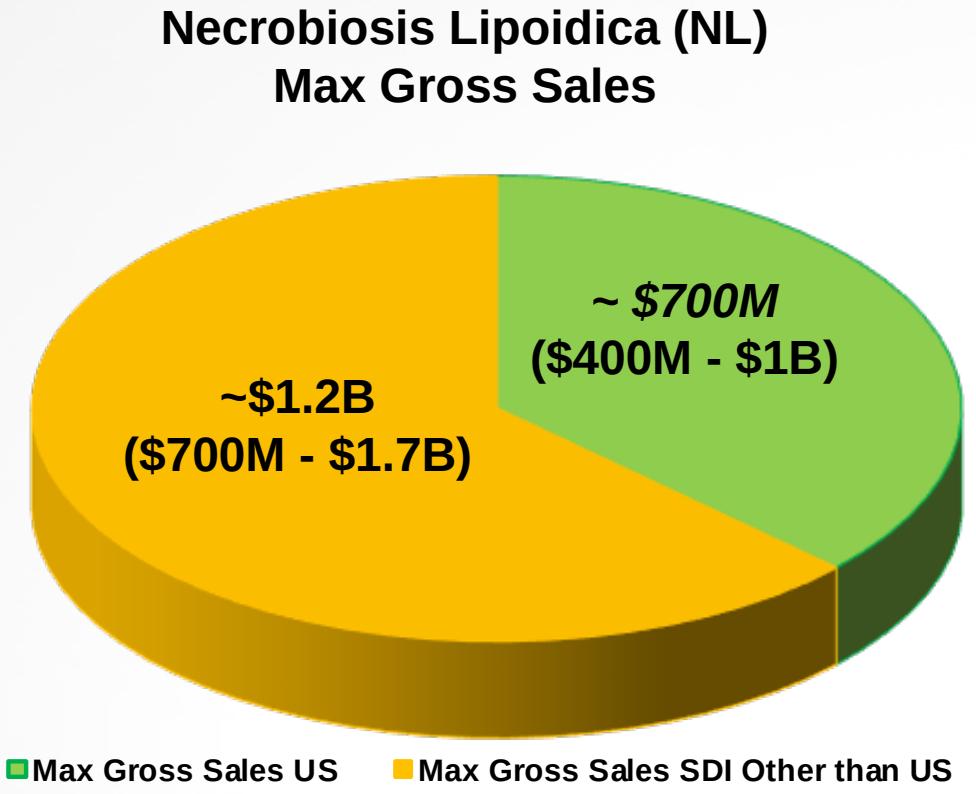
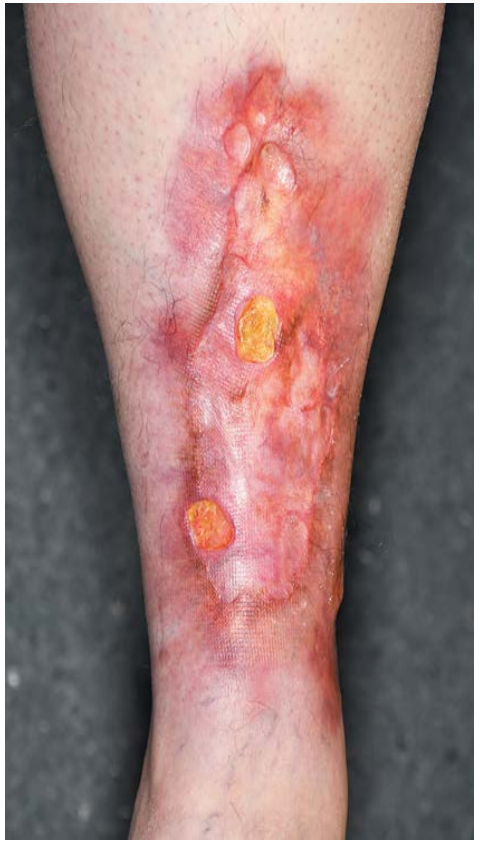
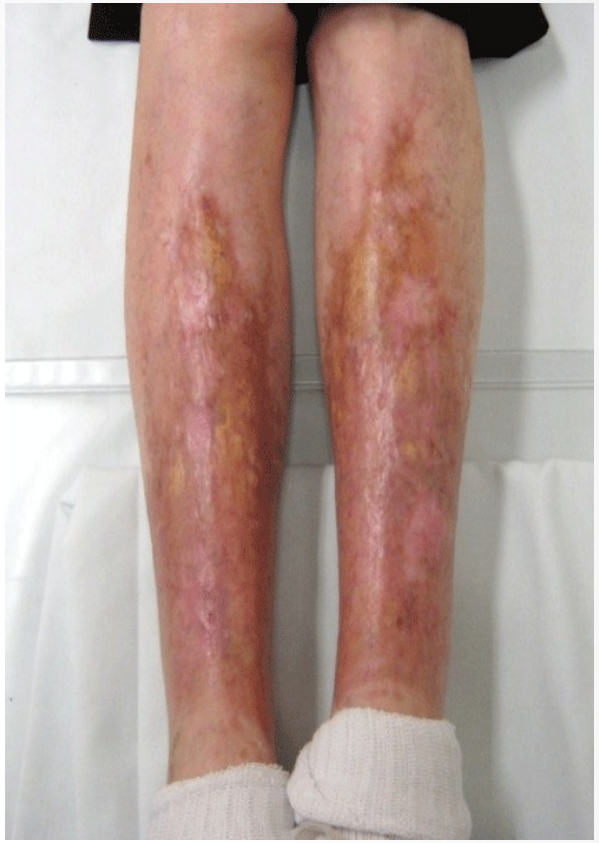
High Value: NL Market Opportunity
Max Annual Gross Sales > *$1.0 B*







- 74,000 – 185,000 Patients in US
- 200,000 – 500,000 Patients in High Sociodemographic Index (SDI) Countries

Source: Muller SA, et al. Arch Dermatol. 1966; Jockenhöfer F, et al, J Dtsch Dermatol Ges. 2016; Company

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High Value: Faster Time to Market

- Development of PCS-499 can be expedited given many of the NDA required chemistry, manufacturing, pre-clinical and Phase 1 studies have already been conducted by Concert Pharmaceuticals.

- In our NL pre-IND (Investigation New Drug) meeting with the FDA, FDA agreed to the possibility of 1 pivotal trial given the orphan designation, seriousness of NL and no approved treatment.

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High Value: Differentiation from other Treatments

- Since there is no standard of care for NL and the treatment options presently used result in minimal efficacy (even off-label use of PTX, the non-deuterated parent drug of PCS-499), a new efficacious-safe drug would have the opportunity to differentiate itself from existing therapy
- In pre-clinical toxicology studies, the maximum tolerated dose for PCS-499 > PTX
- In Phase 1 and Phase 2 studies, 1.8 gm/day (900 mg b.i.d.) of PCS-499 administered orally was well tolerated while PTX is not well tolerated at doses > 1.2 gm/day (400 mg t.i.d.) and not tolerated even at 1.2 gm/day for some patients (1.2 gm/day is the max FDA recommended dose)
- After PCS-499 administration, the same active moieties exist systemically as in PTX but the amounts of key active moieties after the same dose of PCS-499 and PTX are more than 2 times greater after PCS-499 administration

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Lower Risk: PCS-499 Pharmacology, Toxicology, PK Already Evaluated

- Pharmacology of PCS-499 and PTX has been evaluated
- The toxicology in animals and safety in humans for PCS-499 and PTX has been evaluated
- The CMC for PCS-499 has been defined and already being refined for NDA submission
- The single and multiple dose PK for the final PCS-499 product has been completed
- All pre-clinical and Phase 1 studies required prior to Phase 3 trial have been completed
- Other toxicology (eg, carcinogenicity) and Phase 1 (eg, drug interaction studies) requirements for NDA approval are to be discussed at our next meeting with FDA

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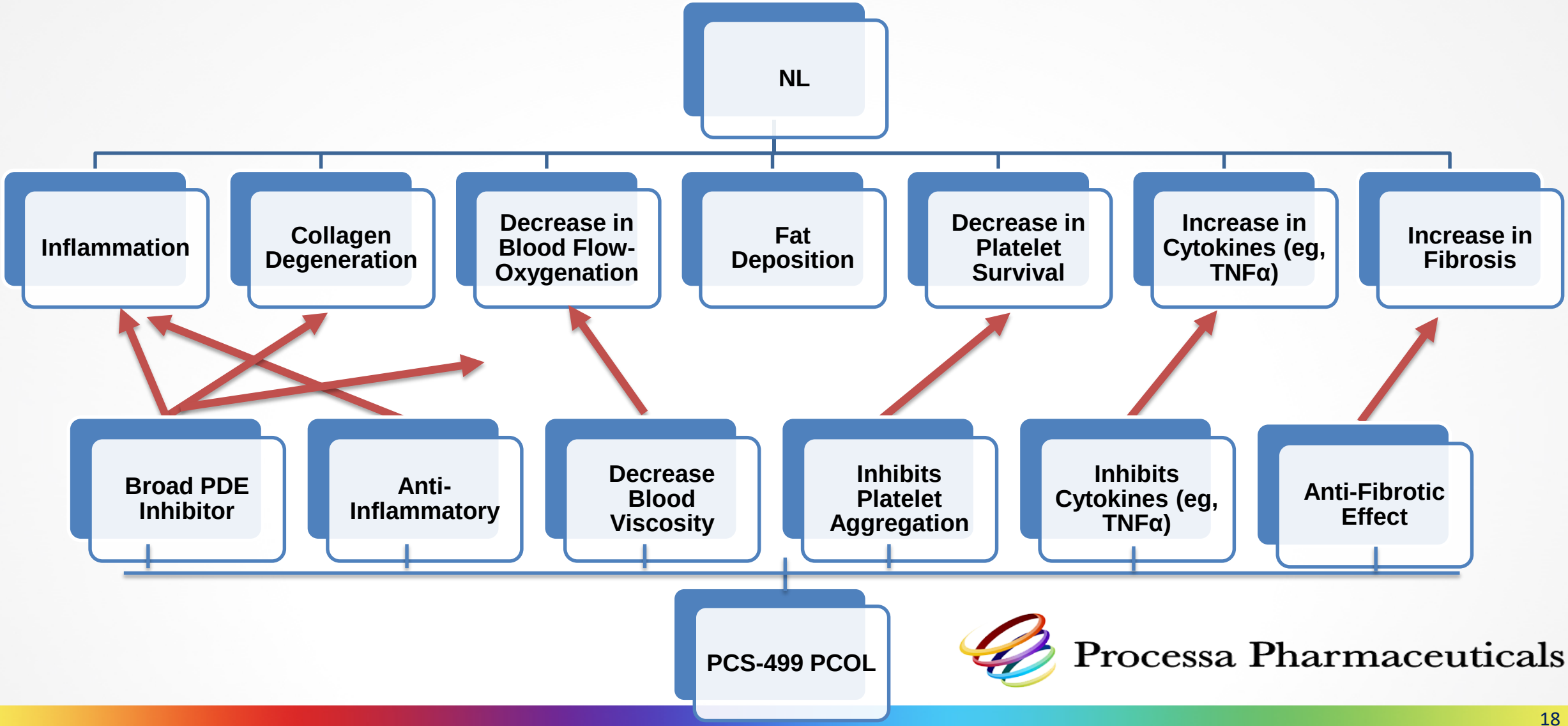
Lower Risk: PCS-499 is the Only Drug Other than PTX to Target the Many NL Pathophysiological Changes



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Lower Risk: Clinical Evidence Exists Supporting the Use of PTX and PCS-499 in NL

- PTX is used OFF-LABEL and response can start after 1 month with significant improvement within 3-12 months (published case studies and clinical experience)
- PTX does not have widespread use; a small percentage of patients respond at the maximum tolerated dose of PTX while many patients cannot tolerate the highest dose of PTX
- Increasing PTX dose beyond 1.2 gm/day (400 mg t.i.d.) to achieve higher response rate results in dose limiting side effects (nausea, vomiting, headaches)
- The PCS-499 Phase 2 NL trial has demonstrated that 1.8 gm/day (900 mg b.i.d.) is well tolerated and efficacy has been observed in patients with severe NL

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Status of PCS-499 NL Program

- Defined development program in pre-IND collaborative meeting with FDA; FDA stated that 1 pivotal study may be acceptable for NL
- Received Orphan Designation (7 years of Market Exclusivity upon approval)
- PCS-499 IND cleared by FDA for PCS-499 Phase 2a safety/tolerability trial in 12 NL patients
- Enrollment complete in Phase 2a trial; trial to be completed March 2020
- PCS-499 was well tolerated at 1.8 gm/d in healthy human volunteers and NL patients.
- Efficacy was seen in severe NL patients with open ulcers when treated with PCS-499
- Requested FDA meeting to define Special Protocol Assessment (SPA) for larger randomized pivotal trial (Phase 2b/3); trial anticipated to start in 2020 and complete in 2023

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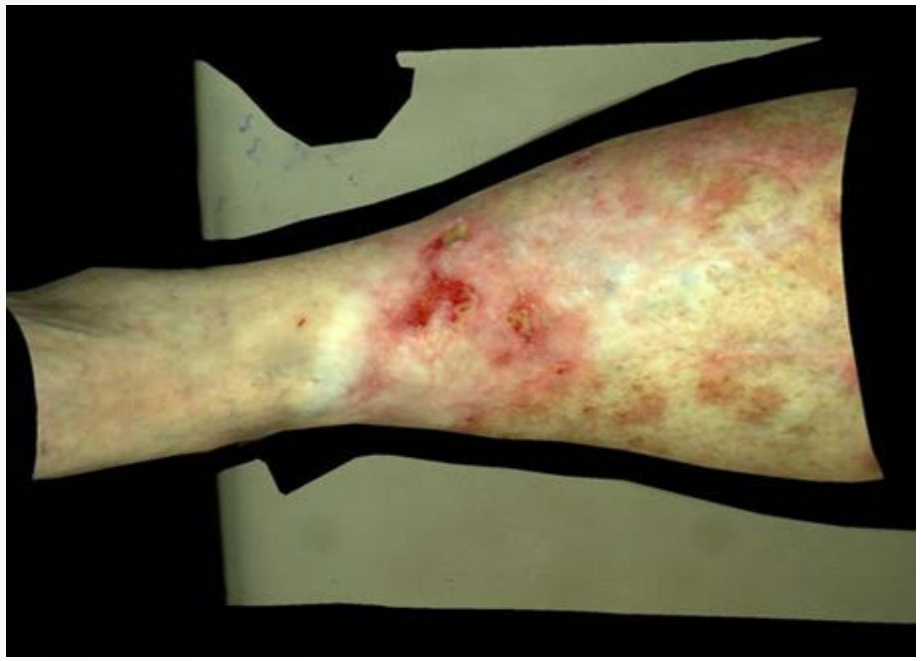
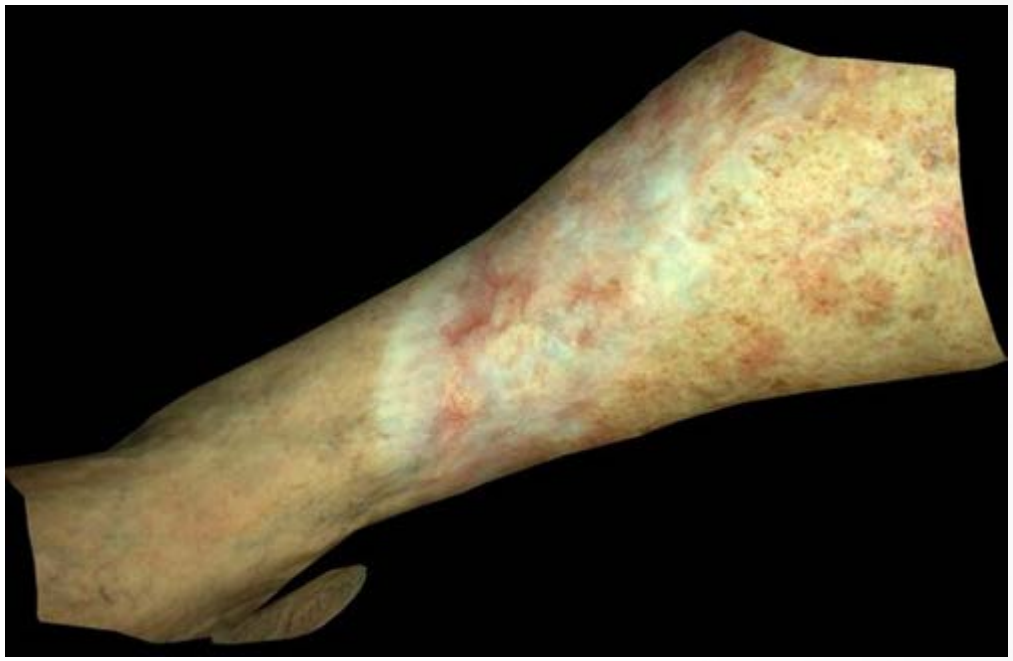
Status of Safety/Tolerability PCS-499 NL Trial

- PCS-499 well tolerated at 1.8 gm/d and efficacy seen in the two NL patients with open ulcers; the ulcers in these severe NL patients completely closed
- Ulcers occurring from physical contact during the study were also completely closed



Baseline



Month 5 – Complete Closure

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PCS-100 Anti-fibrotic and Anti-inflammatory Drug

- Affects collagen expression and TGF-β pathway

- History
  - Incomplete tox package but FDA cleared IND for Duchenne Muscular Dystrophy (DMD)
  - Efficacy observed in pediatric DMD patients
  - Previous company mismanaged DMD trial resulting in a Serious Adverse Event
  - Placed on clinical hold, later removed off clinical hold

- Potential Indications (Processa plans to first develop PCS-100 in an adult indication, then move back to pediatric indications after more is known about therapeutic window)
  - Idiopathic Pulmonary Fibrosis, Scleroderma, other fibrotic related conditions in adults
  - DMD or other fibrotic related conditions in pediatric patients

- Plan to meet with FDA in 2020 to define the development in an adult fibrotic condition where there is existing clinical evidence that a drug with ant-fibrotic properties would be efficacious

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Financial Metrics
&
12 – 18 Month Catalysts

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Processa Financial Overview

OTCQB (1/09/20)	PCSAD - $18.00/share
Market Cap (1/09/20)	$99 M
Shares Outstanding	5.5 M Shares
Prior Cash Investment in Processa	$11.8 M
Present Cash Balance (1/09/20)	$770 K
Convertible Line-of-Credit	$1.4 M (full $1.4 M still available)
Remaining Phase 2 Trial Expenses	$400 K to be paid through 1H2020
PCSAD Insider Ownership %	70%
Nasdaq Listing	Presently working on Q1-2020 Nasdaq listing and raising funds to support catalyst over the next 12-18 months

Catalysts Over the Next 12 – 18 Months

- Obtain Nasdaq listing, raise funds to support the catalysts briefly described below
- Development of PCS-499
  - Complete Phase 2 trial (safety, tolerability, efficacy trial) in NL patients (1H2020)
  - Meet with FDA to discuss remaining requirements for NDA submission(1Q2020)
  - Submit Special Protocol Assessment (SPA) for Phase 2/3 pivotal trial; initiate trial (2H2020)
  - Out-license PCS-499 for development and commercialization outside the U.S.
- Development of PCS-100
  - Meet with FDA on first IND indication for adults (1H2020)
  - Submit IND for safety/tolerability trial in healthy volunteers in order to better define therapeutic window in adults; initiate trial (2H2020)
- Development of new drug asset(s)
  - Acquire at least one other drug asset that fits the Processa model (2020)
  - Meet with FDA on the development program for the drug and indication (2020)
  - Depending on previous clinical trials, design the next trial; obtain FDA approval to conduct next clinical trial

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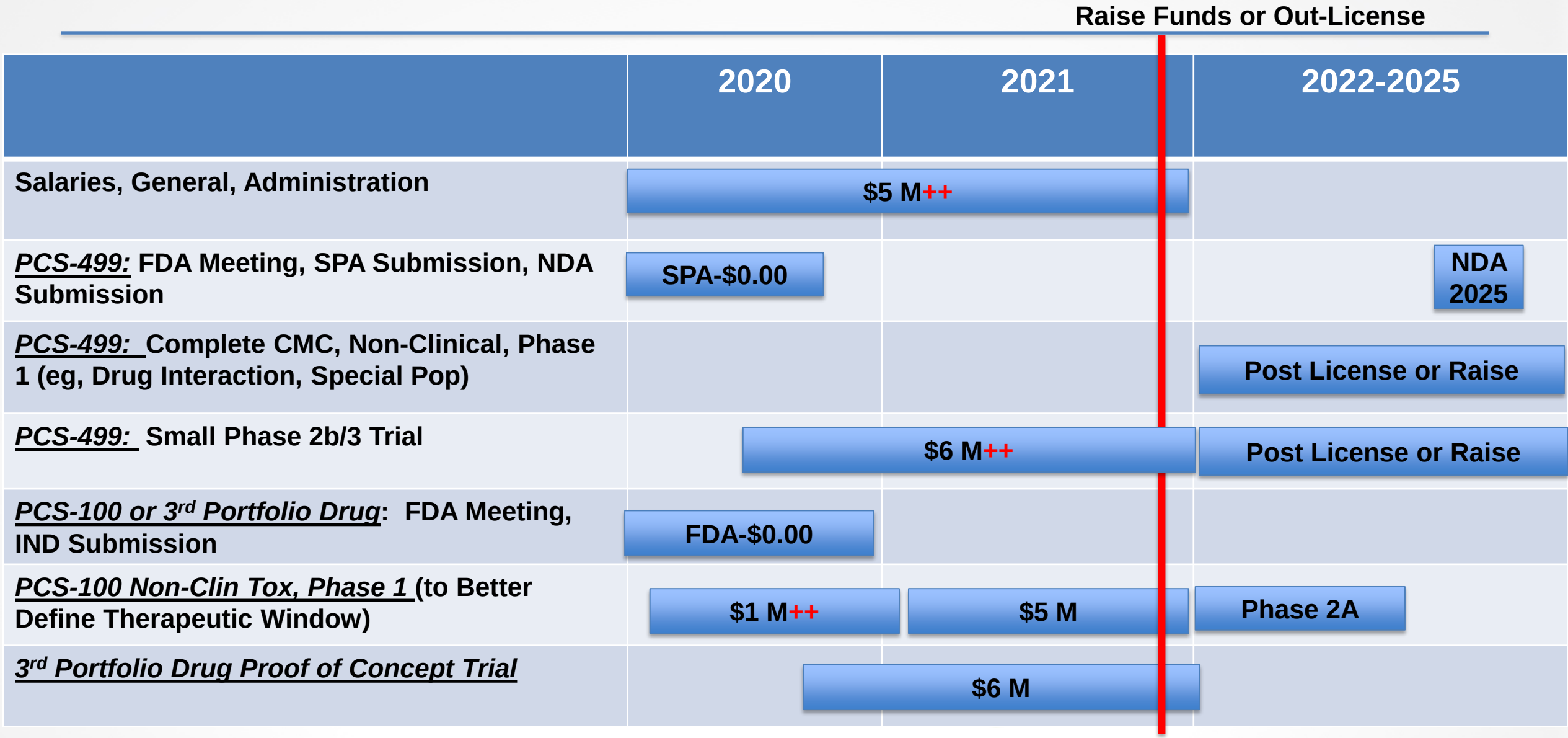
Use of $12 M++ Proceeds



Use of $17 M ++ – $31 M** Proceeds

Out-License or Raise Funds

	2020	2021	2022-2024
Salaries, General, Administration	$5 M++ **		
PCS-499: FDA Meeting, SPA Submission, NDA Submission	SPA-$0.00		NDA 2024
PCS-499: Complete CMC, Non-Clinical, Phase 1 (eg, Drug Interaction, Special Pop)			Post Interim Analysis
PCS-499: Larger Phase 2b/3 Adaptive Pivotal Trial with Interim Analysis	$11 M to Interim Analysis++ **		$10 M to Completion
PCS-100 or 3rd Portfolio Drug: FDA Meeting, IND Submission	FDA-$0.00		
PCS-100 Non-Clin Tox, Phase 1 (to Better Define Therapeutic Window)	$1 M++ **	$5 M**	Phase 2A
3rd Portfolio Drug Proof of Concept Trial		$6 M**	

Summary

Focused on Acquiring and Developing Drug Products for Patients Needing Treatments to Extend Survival and/or Significantly Improve Quality of Life

- Building a portfolio of high value drugs for patients with unmet medical need conditions
- Experienced management, development team with a track record of successful FDA approvals and value creation
- Present portfolio of two drugs with addressable markets > $1.5 B
  - Clinical evidence of efficacy for both drugs decreasing the risks associated with development
  - Expanding each drug to additional indications could potentially occur in the future
  - Additional drug acquisitions for the portfolio are being negotiated
- Overhead burn rate was less than $2.5 M in 2019
- Complete capital raise of at least $12 million, up-list shares to the Nasdaq Capital Market Q1-2020
- Several value inflection points over the next 12 – 18 months

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